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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/521,195	03/07/2000	Jun-ichi Nezu	06501-057001	9418
26161 75	26161 7590 07/10/2003			
FISH & RICHARDSON PC			EXAMINER	
225 FRANKLIN ST BOSTON, MA 02110			MERTZ, PREM	MA MARIA
			ART UNIT	PAPER NUMBER
			1646	0~
		·	DATE MAILED: 07/10/2003	$\approx$

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No. 09/521,195 Applicant(s)

Examiner

Ibaraki et al.

Office Action Summary

Prema Mertz

Art Unit 1646



	The MAILING DATE of this communication appears o	n the cover sheet with the correspondence address			
D. 1. 4.6		n the cover sneet with the correspondence address			
A SHO THE N - Extensi mailing - If the p - If NO p - Failure - Any re	ORTENED STATUTORY PERIOD FOR REPLY IS SET TO MAILING DATE OF THIS COMMUNICATION.  Joins of time may be available under the provisions of 37 CFR 1.136 (a). In not a date of this communication.  Joins of time may be available under the provisions of 37 CFR 1.136 (a). In not a date of this communication.  Joins of time may be available under the provisions of 37 CFR 1.136 (a). In not a date of this communication.  Joins of time may be available under the provisions of 37 CFR 1.136 (a). In not a date of this provisions of time may be available under the provisions of 37 CFR 1.704(b).	statutory minimum of thirty (30) days will be considered timely.  d will expire SIX (6) MONTHS from the mailing date of this communication.  application to become ABANDONED (35 U.S.C. § 133).			
Status					
1).💢	Responsive to communication(s) filed on Jun 25, 20	003			
2a) 🗌	This action is <b>FINAL</b> . 2b) 💢 This action	on is non-final.			
3) 🗆	3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.				
Disposit	tion of Claims				
4) 💢	Claim(s) 1-7, 27, and 29-49	is/are pending in the application.			
4	la) Of the above, claim(s) 27	is/are withdrawn from consideration.			
5) 💢	Claim(s) <u>5 and 29</u>	is/are allowed.			
6) 💢	Claim(s) 1, <b>6</b> , 7, and 30-34				
7) 💢	Claim(s) 2-4 and 35-49				
8) 🗌		are subject to restriction and/or election requirement.			
	ation Papers				
9) 🗆	The specification is objected to by the Examiner.				
10)	The standard but the Functions				
	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).				
11)	The second by the Evening				
	If approved, corrected drawings are required in reply to this Office action.				
12)	The oath or declaration is objected to by the Examir	ner.			
Priority under 35 U.S.C. §§ 119 and 120					
13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).					
a) [	$\square$ All b) $\square$ Some* c) $\square$ None of:				
	1. $\square$ Certified copies of the priority documents have	e been received.			
2. Certified copies of the priority documents have been received in Application No.					
*5	3. Copies of the certified copies of the priority do application from the International Bures see the attached detailed Office action for a list of the				
14) 🗆					
a) The translation of the foreign language provisional application has been received.					
15)	Acknowledgement is made of a claim for domestic				
Attachm					
	otice of References Cited (PTO-892)	4) Interview Summary (PTO-413) Paper No(s).			
2) 🗌 N	otice of Draftsperson's Patent Drawing Review (PTO-948)	5) Notice of Informal Patent Application (PTO-152)			
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)					

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**DETAILED ACTION** 

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1. Claims 8-26, 28 have been canceled previously. Claims 1-7, 29, amended claims 30, 32, 33-

34, and new claims 35-49 (Paper No. 24, 6/25/03), are under consideration.

2. Receipt of applicant's arguments and amendments filed in Paper No. 24 (6/25/03) is

acknowledged.

3. The following previous rejections and objections are withdrawn in light of applicants

amendments filed in Paper No. 24, 6/25/03:

(i) the rejection of claims 1-4, 6-7, 30-34 under 35 U.S.C. § 112, first paragraph; and

(ii) the rejection of claims 30, 33-34 under 35 U.S.C. § 112, second paragraph.

4. Applicant's arguments filed in Paper No. 24 (6/25/03), have been fully considered and were

persuasive. The new issue is stated below.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in

a prior Office action.

Claim rejections-Double Patenting

Non-statutory double patenting rejection (obviousness-type)

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded

in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper

timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment

by multiple assignees. See In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re

Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ

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761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6a. Claims 1, \$\infty\$7, 30, 31, 32, 33, 34, are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 09/798,743. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim the same polypeptide.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 1 in the instant application claims a polypeptide comprising the amino acid sequence that is at least 76% identical to SEQ ID NO:1. Claims 3, 12, 14, 28, 35-38 of U.S. Application No. 09/798,743 (having all common inventors with the instant application), claims a pharmaceutical composition of the polypeptide comprising the amino acid sequence of SEQ ID NO:1. However, SEQ I D NO:1 of U.S. Application No. 09/798,743 is 76.9% identical with SEQ ID NO:1 in the instant application. Therefore, the claims in the instant application are generic to the claims in the

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corresponding application and encompass subject matter to which the claims in 09/798,743 are a

species. However, the instant claims are obvious from the claims in 09/798,743 because the claims

in 09/798,743 are directed to one specific embodiment encompassed by the instant claims. The

products in 09/798,743 are included in the instant claims. It would have been obvious to one of

ordinary skill in the art at the time the present invention was made, that a polypeptide comprising

the amino acid sequence that is at least 76% identical to SEQ ID NO:1 included the polypeptide

comprising the amino acid sequence of SEQ ID NO:1 as recited in U.S. Application No.

09/798,743.

Furthermore, with respect to the "pharmaceutical composition" limitation in 09/798,743, it

would have been prima facie obvious to one of ordinary skill in the art at the time that the invention

was made, to merely admix a carrier with a known protein, and obtaining such does not render the

resulting pharmaceutical composition patentable if it would have been obvious to formulate the

protein with a carrier relative to its art intended use (In re Rosicky 125 USPQ 341).

The claims in 09/798,743 if infringed upon would also result in infringement of the claims

of the instant application. Allowance of the pending claim, therefore, would have the effect of

extending the enforceable life of the claims in 09/798,743 beyond the statutory limit.

This rejection can only be withdrawn if a terminal disclaimer is filed, so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent.

Conclusion

Claims 5, 29 are allowable.

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Claims 2-4, 35-49 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form.

## Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 305-3014 or (703 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 746-5300.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Prema Mertz Ph.D. Primary Examiner Art Unit 1646 July 8, 2003